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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/601,731	06/23/2003	Joseph Raymond Faryniarz	J6829(C)	7564

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EXAMINER

GOLLAMUDI, SHARMILA S

ART UNIT	PAPER NUMBER
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1616

DATE MAILED: 02/27/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/601,731	Applicant(s) FARYNIARZ ET AL.	
	Examiner Sharmila S. Gollamudi	Art Unit 1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 November 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 3-16 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 3-16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|-----------------------------------------------------------------------------------------|-----------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Receipt Amendments/Remarks and the Terminal Disclaimer filed 11/10/05 is acknowledged.

Claims **1 and 3-16** are pending in this application. Claim 2 is cancelled.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 8-9 and 12-13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

New claims 8-9 and 12-13 recite “wherein the malonic acid is present in an amount...”, which is vague and indefinite since it is unclear if applicant is referring to the malonic acid salt or the malonic acid itself since the parent claims requires malonic acid in the salt form. Further clarification is requested.

Claim Rejections - 35 USC § 102

1) The rejection of claims 1, 4, and 6-7 under 35 U.S.C. 102(b) as being anticipated by WO 00/61107 to Beerse et al is hereby withdrawn view of the amendment of 11/10/06.

2) The rejection of claims 1, 4, and 6-7 under 35 U.S.C. 102(b) as being anticipated by Apperson et al (2,586,288) is withdrawn view of the amendment of 11/10/06.

3) The rejection of claims 1 and 4-7 under 35 U.S.C. 102(b) as being anticipated by Jokura et al (5,641,495) is withdrawn view of the amendment of 11/10/06.

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Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1 and 3-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jokura et al (5,641,495).

Jokura teaches a skin cosmetic containing having an excellent moisturizing effect comprising: (A) a ceramide or a pseudoceramide; (B) a dicarboxylic acid; and (C) a salt of a dicarboxylic acid. See abstract. The composition is used for treating dry skin in the winter and applicable to the skin around the eyes to prevent crow's feet, i.e. fine lines around the eyes. See column 5, lines 35-39. The composition softens the keratinous layer. See column 1, lines 7-20.

Jokura teaches examples of the dicarboxylic acid (B) include **malonic** acid, succinic acid, fumaric acid, maleic acid, glutaric acid, adipic acid, phthalic acid, and terephthalic acid. The dicarboxylic acid salt (C) include alkali metal (for example, sodium, potassium) salts; alkali earth metal (for example, calcium, magnesium) salts; **alkanolamine** (for example,

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triethanolamine) salts; basic amino acid (for example, lysine, arginine) salts and **ammonium** salts. Note that the term amine encompasses Jokura's alkanolamines, arginine, lysine, and ammonium. These dicarboxylic acid salt may be added in the form of a salt at the step of the preparation of the skin cosmetic of the present invention. Alternatively, an acid may be added followed by the addition of an alkali (sodium hydroxide, etc.) to thereby form the aimed salt via *neutralization* in the system. To achieve a sufficient moisturizing effect while avoiding excessive irritation, it is preferable that the content of components (B) and (C), falls within a range of from 0.01 to 20% by weight, still preferably from 0.05 to 15% by weight and preferably 0.01 to 10% by weight. To achieve a sufficient moisturizing effect while avoiding irritation due to the acid, it is preferable that the molar ratio of the components (B) to (C) falls within a range of from 1/9 to 9/1, still preferably from 2/8 to 8/2. See column 3, lines 30-60. Furthermore, Jokura teaches regulating the pH value of the skin cosmetic, which contains the components (B) and (C), to pH 3 to 10, still preferably to pH 3 to 9, to avoid the irritation observed at a pH value less than 3 or exceeding 10. See column 3, lines 60-65. The examples utilize a pH of 4.1. When oily substances are used as the carrier, the content of the oily substance in is a range from 0.01 to 50% by weight. See column 4, lines 14-16. When water, ethanol and/or water-soluble polyhydric alcohols are employed as the carrier, the content is preferably from 0.01 to 95% by weight. See column 4, lines 30-35.

Jokura et al do not specify the acid to salt molar ratio of component (C) (the degree of neutralization).

However, it would have been obvious to one of ordinary skill in the art at the time the invention was made to look to the guidance provided by Jokura et al and manipulate the acid to

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salt ratio of component (C). One would have been motivated to manipulate the ratio of the salt to acid since partial or full neutralization of the acid by the salt (salt acts as the neutralizing agent) adjusts the pH of the composition. Thus, one would have been motivated to utilize the desired acid: salt ratio depending on the desired pH of the composition. For instance, Jokura teaches the importance of avoiding skin irritation due to the acid; thus the pH must be above 3 and below 10 (see column 3, lines 30-65). Therefore, a skilled artisan would have been motivated to use a sufficient amount of salt to either partially or fully neutralize the acid in the composition to render a pH that does not irritant the skin wherein using equimolar amounts of the salt and acid (full neutralization) would contribute to the overall increase of the pH of the composition whereas partial neutralization of the acid would contribute to the overall decrease of the pH of the composition since the compound is in a slightly acidic form. Additionally, it should be noted that generally differences in concentrations, such as the instantly claimed molar ratio of acid to salt, do not support the patentability of subject matter that is encompassed by the prior art unless there is evidence indicating such as concentration is critical. See *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

With regard to the recitation of “wherein the composition exhibits a Flexibility Value greater than 1 in the Porcine Skin Test”, it is the examiner’s position that Jokura’s composition will implicitly have a Flexibility value of greater than 1 since the instant disclosure on page 5 states that malonate salts impart the flexibility value to the composition and they impart a value of at least 1.1. Secondly, the prior art teaches the same malonic acid salt in the same weight percent. Therefore, the prior art’s composition and the instant composition, which recites open-

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claim language, are identical, it is the examiner's position that they will exhibit the same property, i.e. the instant flexibility value.

Response to Arguments

Applicant argues that experiments performed by applicant demonstrate that malonate salts are much better than glycolate or succinate salts with respect to improving skin flexibility. Applicant argues that Jokura is silent about the nature of the dicarboxylic acid salts. Applicant argues that Jokura does not exemplify malonic acid and only mentions it once. Further, applicant argues that the only dicarboxylic acid exemplified is succinic. Thus, applicant argues that a skilled artisan would not have been motivated to select malonate over succinate especially in view of applicant results demonstrated in example 9.

Applicant's arguments filed 11/10/05 have been fully considered but they are not persuasive. Firstly, the examiner points out that a reference need not exemplify an embodiment to anticipate an invention or render it obvious. Further, the fact that the examples do not utilize the embodiments is not a teaching away. "Disclosed examples and preferred embodiments do not constitute a teaching away from the broader disclosure or nonpreferred embodiment". In re Susi, 440 F.2d 442, 169 USPQ 423 (CCPA 1971).

The examiner points out that malonic acid does not appear in a laundry list of acids to utilize and the acids taught by Jokura are sufficiently limited for one to immediately envisage the use of instant malonic acid salt. The only teaching lacking is the express molar ratio of acid to salt. Thus, although the examiner notes example 9 in the instant specification, it is the examiner's position that this is not sufficient to overcome Jokura since Jokura clearly envisages malonic acid. Assuming *arguendo* that the use of malonic acid is not immediately envisaged and a skilled

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artisan would have to specifically pick malonic acid, the examiner notes the following about the unexpected results the applicant relies on to overcome Jokura. Example 9 utilizes two specific malonic acid salts, i.e. ammonium and dimethylethanolammonium salt, and the instant independent claims are broadly directed to the genus "salts" wherein the examples utilizes amine salts specifically. Therefore, it is unclear if the same flexibility is imparted by the entire genus since the term salt is extremely broad. Moreover, the examiner notes that the example in the specification does not set forth the concentration of each acid salt utilized, i.e. the prior art's and the instant, or the molar ratio of the acid to salt (which applicant claims is critical). Therefore, it is unclear if a multitude of variables are present to effect the results, i.e. the concentration, the molar ratio of acid to salt. For instance, if applicant utilized a weight percent of 8% of the malonate salt and compared it with a 4% succinate salt, the results may be influenced by the concentration rather than the type of acid salt utilized.

Thus, as set forth in the rejection above, it is the examiner's position that the manipulation of the salt to ratio is known and routine to a skilled artisan. It is known in the art that the addition of a salt to an acid neutralizes the acid functionality and depending on the concentration of the salt, the acid may either fully or partially neutralize it. The applicant has not shown or demonstrated any unexpected results to overcome Jokura since "generally difference in concentrations do not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such as concentration is critical." See *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). The examiner also points out that Jokura teaches the criticality of utilizing the acid and acid salt form in a specific ratio to render a non-irritating pH. Thus, it is the examiner's position that Jokura also provides the motivation to manipulate the

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acid/salt ratio, i.e. to render a pH that is not irritating. The examiner suggests providing the unexpectedness of the molar ratio since the prior art teaches the malonic acid salt.

Claims 1, 3-4, 6-9, 11-13, and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 00/61107 to Beerse et al.

Beerse discloses an antimicrobial wipe that is impregnated with an antimicrobial cleansing composition. See abstract. Specifically example 14 discloses a composition comprising 3.20% sodium malonate, additional components, and the balance water (84.03% of the carrier). The wipe is suitable for application to the human skin to remove oil and dirt. Further, the composition is useful for treatment of acne and improvement of skin appearance. The improvement includes providing a smoother and more even appearance of the skin and regulating the signs of aging (wrinkles, fine lines, sagging, loss of skin's firmness, etc). See page 4, lines 25-36 and in particular page 5, lines 1-30. Beerse teaches the proton donating agent selected from acids such as glycolic, citric, malonic, etc. in an amount of 0.1-10%, preferably 0.5-8% is either directly added or added in its conjugated base of the desired acid and the acid remains at least in a partially undissociated form. Further, Beerse teaches that the pH of the invention is critical since the benefits of the invention lie in the undissociated acid form the proton donating agent remain on the skin and the pH should be 3-6 and preferably 3-5, wherein the pH is adjusted accordingly. Beerse teaches the manipulation of the pH based on the acid and base. See page 18.

Beerse does not specify the acid to salt molar ratio of component (C) (the degree of neutralization).

However, it would have been obvious to one of ordinary skill in the art at the time the invention was made to look to the guidance provided by Beerse et al and manipulate the acid to salt ratio of component of the malonate salt, i.e. sodium malonate. One would have been motivated to manipulate the ratio of the salt to acid since partial or full neutralization of the acid by the salt (salt acts as the neutralizing agent) adjusts the pH of the composition. Thus, one would have been motivated to utilize the desired acid: salt ratio depending on the desired pH of the composition. For instance, Beers teaches the importance of a pH between 3 and 6 and buffering it accordingly. Thus, depending on the pH desired, a skilled artisan would have been motivated to use a sufficient amount of salt to either partially or fully neutralize the acid in the composition to render the desired pH, wherein using equimolar amounts of the salt and acid (full neutralization) would contribute to the overall increase of the pH of the composition whereas partial neutralization of the acid would contribute to the overall decrease of the pH of the composition since the compound is in a slightly acidic form. Additionally, it should be noted that generally differences in concentrations, such as the instantly claimed molar ratio of acid to salt, do not support the patentability of subject matter that is encompassed by the prior art unless there is evidence indicating such as concentration is critical. See *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

With regard to the recitation of “wherein the composition exhibits a Flexibility Value greater than 1 in the Porcine Skin Test”, it is the examiner’s position that Beerse’s composition will implicitly have a Flexibility value of greater than 1 since the instant disclosure on page 5 states that malonate salts impart the flexibility value to the composition and they impart a value of at least 1.1. Secondly, the prior art teaches the same malonic acid salt in the same weight

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percent. Therefore, the prior art's composition and the instant composition, which recites open-claim language, are identical, it is the examiner's position that they will exhibit the same property, i.e. the instant flexibility value.

Response to Arguments

Applicant argues that Beerse does not render the instant invention obvious since Beerse only utilizes it has a proton donating agent and for no other reasons. Applicant argues that it appears that Beerse does not ascribe any type of activity to the malonate species itself and only uses it has a proton-donating agent.

Applicant's arguments filed 11/10/05 have been fully considered but they are not persuasive. Firstly, the examiner points out that the argument that the prior art utilizes the acid for another reason from the applicant is not enough to overcome the prior art. The fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985). In instant case, applicant is claiming a product and method of using a product that comprises a malonate salt. Beerse teaches a composition comprising sodium malonate. Thus, the fact that Beerse may use the malonic acid salt for a different purpose than the applicant is irrelevant.

The examiner suggests providing the unexpectedness of the molar ratio since the prior art clearly teaches the malonic acid salt.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed.

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Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

1) The rejection of claims 1-3 and 5-7 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-7 and 9 of copending Application No. 10/347982 is withdrawn in view of the filing of the Terminal Disclaimer of 11/10/05.

2) The rejection of claims 1-7 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-6 of copending Application No. 10/374300 is withdrawn in view of the filing of the Terminal Disclaimer of 11/10/05.

3) The rejection of claims 1-5 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-2 and 7 of copending Application No. 10/601819 in view of Clark (Dermatology Times, February 2002, pg. 78) is withdrawn in view of the filing of the Terminal Disclaimer of 11/10/05.

4) The rejection of claims 1-5 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-6 of copending Application No. 10/601856 in view of JP 61215318 (entire document) is withdrawn in view of the filing of the Terminal Disclaimer of 11/10/05.

5) The rejection of claims 1-5 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-5 of copending Application No. 10/767679

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in view of Nakatsu et al (5,965,518) is withdrawn in view of the filing of the Terminal Disclaimer of 11/10/05.

Conclusion

All the claims are rejected.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

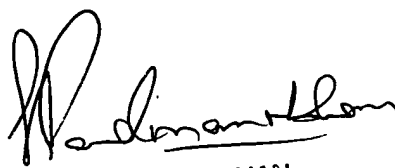
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharmila S. Gollamudi whose telephone number is 571-272-0614. The examiner can normally be reached on M-F (8:00-5:30), alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on 571-272-0887. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Sharmila S. Gollamudi
Examiner
Art Unit 1616



SHARMILA S. GOLLAMUDI
SUPERVISORY TECHNICIAN